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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,096	11/22/2000	Ernest G. Hope	D40182	4236
22434 7590 02/08/2007 BEYER WEAVER LLP P.O. BOX 70250 OAKLAND, CA 94612-0250			EXAMINER YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER
			1643	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/08/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/722,096	<b>Applicant(s)</b> HOPE, ERNEST G.	
	<b>Examiner</b> Christopher H. Yaen	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 101-106, 108-141 and 173-175 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 101-106, 108-141, and 173-175 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

***Re: Hope***

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/25/2007 has been entered.
2. The amendment filed 1/25/2007 is acknowledged and entered into the record. Accordingly, claims 1-100, 107, and 142-172 are canceled without prejudice or disclaimer, and claims 173-175 are newly added.
3. Claims 101-106, 108-141, and 173-175 are pending and examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections Maintained - 35 USC § 102***

5. The rejection of claims 101-110, 118-120, 122-128, 131-141, and now 173-175 under 35 USC § 102(b) as being anticipated by Lu *et al* is maintained for the reasons of record. Applicant argues that the instant invention is differs from the cited reference of Lu *et al* in that the cells instantly claimed are cells which possess a cytotoxic activity against cancer cells which "exceeds that of a population of cells produced by growing

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the same lymphocytes in a standard flask". Specifically, applicant contends the instant cell population has a material difference from that of Lu *et al* because the instant cells were produced differently (i.e. in a closed agitating system) and this culturing method produced cells which have 35% higher cytolytic activity. From this applicant concludes that the population of cells is materially different and produced different anti-tumor activities. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In addition, the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). In this case, applicant has only indicated that the method of producing the product was different and has not specifically indicated that the product produced by this method produced any structural difference. Moreover, it can be argued that culturing the cell population by agitation, as claimed, only further purified what was already in characterized by Lu *et al* because applicant indicates that the "same population of lymphocytes" (differing only in culturing methods)

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increase its cytolytic activity by 35% over the cell population cultured in standard flasks. This would indicate that there was no "structural" difference imparted by the method because both cell populations have cytolytic activity. Therefore the method of making the instant population does not have any patentable weight on the claimed cell population.

The Patent Office bears a lesser burden of proof in making out a prima facie for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). In this case, applicant has not met the burden of establishing that the instantly claimed cell population produced by the claimed method has any structural difference over the teachings of Lu *et al.* Instead, applicant has only provided evidence that the method produced a cell population with higher activity.

Therefore, the rejection of claims under 35 USC 102(b) is maintained for the reasons of record.

#### ***Claim Rejections Maintained - 35 USC § 102***

6. The rejection of claims 101-110, 122-128, 131-141, and now 173-175 under 35 USC § 102(b) as being anticipated by Alvernas *et al.* is maintained for the reasons of record. Applicant's arguments are substantially similar to those already presented and rebutted (see above). Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

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Therefore the rejection of claims under 35 USC 102(b) is maintained for the reasons of record.

**NEW REJECTION**

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

7. Claims 101-106, 108-141, and 173-175 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Applicant has amended the claims to recite the cell population's ability to specific lyse cancer cells. Applicant has directed the examiner to page 24 lines 14-23 for specific support. The specification teaches that the cell population of the instant invention has cytotoxic activity against the tumor target OCI-Ly8. The specification does support a cell line that comprises a general cytolytic activity as instantly claimed. Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

***Conclusion***

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher Yaen  
Art Unit 1643  
January 31, 2007

  
CHRISTOPHER H. YAEN  
PRIMARY EXAMINER